



## **DEPARTMENT OF COMMERCE**

### **Patent and Trademark Office**

#### **37 CFR Part 1**

**[Docket No. PTO-P-2022-0008]**

**RIN 0651-AD60**

### **Standardization of the Patent Term Adjustment Statement Regarding Information**

#### **Disclosure Statements**

**AGENCY:** United States Patent and Trademark Office, Department of Commerce.

**ACTION:** Final Rule.

**SUMMARY:** The United States Patent and Trademark Office (USPTO or Office) is revising the rules of practice pertaining to patent term adjustment to require that the patent term adjustment statement regarding information disclosure statements be submitted on an Office form using the appropriate document code. The use of the Office form and document code will streamline certain aspects of prosecution by more accurately capturing and accounting for the patent term adjustment statement without unnecessary back-and-forth between the Office and applicant. It will also conserve resources by eliminating the need for a manual review of the patent term adjustment statement. Applicants who submit a patent term adjustment statement regarding information disclosure statements without using the Office form or the appropriate document code will need to request reconsideration of the patent term adjustment for the information disclosure statement to not be considered a failure to engage in reasonable efforts to conclude the prosecution (processing or examination) of the application. The Office conducts a redetermination of patent term adjustment in response to this request, and the redetermination will include the Office's manual review of the patent term adjustment statement.

**DATES:** This final rule is effective [INSERT DATE 30 DAYS FROM THE DATE OF PUBLICATION IN THE FEDERAL REGISTER], and is applicable to any statement under 37 CFR 1.704(d) filed on or after [INSERT DATE 30 DAYS FROM THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** Kery Fries, Senior Legal Advisor, Office of Patent Legal Administration, at 571-272-7757. You can also send inquiries to [patentpractice@uspto.gov](mailto:patentpractice@uspto.gov).

**SUPPLEMENTARY INFORMATION:** Section 532(a) of the Uruguay Round Agreements Act (URAA) (Pub. L. 103-465, 108 Stat. 4809 (1994)) amended 35 U.S.C. 154 to provide that the term of a patent ends on the date that is 20 years from the filing date of the application, or the earliest filing date for which a benefit is claimed under 35 U.S.C. 120, 121, or 365(c). The URAA also contained provisions, codified at 35 U.S.C. 154(b), for patent term extension due to certain examination delays. Under the patent term extension provisions of 35 U.S.C. 154(b) as amended by the URAA, an applicant is entitled to patent term extension for delays due to interference (which has since been replaced by derivation proceedings), secrecy orders, or successful appellate review. *See* 35 U.S.C. 154(b) (1995). The Office implemented the patent term extension provisions of the URAA in a final rule published in April of 1995. *See* Changes To Implement 20-Year Patent Term and Provisional Applications, 60 FR 20195 (Apr. 25, 1995).

The American Inventors Protection Act of 1999 (AIPA) (Pub. L. 106-113, 113 Stat. 1501, 1501A-552 through 1501A-591 (1999)) further amended 35 U.S.C. 154(b) to include additional bases for patent term extension (which is characterized as “patent term adjustment” in the AIPA). Original utility and plant patents issuing from applications filed on or after May 29, 2000, may be eligible for patent term adjustment if issuance of the patent is delayed due to one or more of the enumerated administrative delays listed in 35 U.S.C. 154(b)(1). Specifically, under the patent term adjustment provisions of 35

U.S.C. 154(b) as amended by the AIPA, an applicant is entitled to patent term adjustment for the following reasons: (1) if the Office fails to take certain actions during the examination and issue process within specified time frames (35 U.S.C. 154(b)(1)(A)); (2) if the Office fails to issue a patent within three years of the actual filing date of the application (35 U.S.C. 154(b)(1)(B)); and (3) for delays due to interference (and now for delays due to derivation proceedings), secrecy orders, or successful appellate review (35 U.S.C. 154(b)(1)(C)). *See* 35 U.S.C. 154(b)(1). However, the AIPA sets forth a number of conditions and limitations on any patent term adjustment accrued under 35 U.S.C. 154(b)(1). Specifically, 35 U.S.C. 154(b)(2)(C) provides, in part, that “[t]he period of adjustment of the term of a patent under [35 U.S.C. 154(b)(1)] shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application,” and that “[t]he Director shall prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application” (35 U.S.C. 154(b)(2)(C)(i) and (iii)). The Office implemented the patent term adjustment provisions of 35 U.S.C. 154(b) as amended by the AIPA, including setting forth circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application, in a final rule published in September of 2000. *See* Changes To Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 FR 56365 (Sept. 18, 2000) (AIPA patent term adjustment final rule). The regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application and the resulting reduction of any patent term adjustment are set forth in 37 CFR 1.704(c)(1) through (14).

This final rule revises the patent term adjustment regulations at 37 CFR 1.704 establishing the circumstances that constitute a failure of an applicant to engage in

reasonable efforts to conclude the prosecution (processing or examination) of an application and any resulting reduction of patent term adjustment. These regulations include a “safe harbor” in 37 CFR 1.704(d), which provides that a paper containing only an information disclosure statement in compliance with 37 CFR 1.97 and 1.98 will not be considered a failure to engage in reasonable efforts to conclude the prosecution (processing or examination) of the application under 37 CFR 1.704(c)(6), (8), (9), or (10) if accompanied by the required statement. The “safe harbor” in 37 CFR 1.704(d) also provides that a request for continued examination, in compliance with 37 CFR 1.114, with no submission other than an information disclosure statement, in compliance with 37 CFR 1.97 and 1.98, will not be considered a failure to engage in reasonable efforts to conclude the prosecution (processing or examination) of the application under 37 CFR 1.704(c)(12) if accompanied by the required statement. The 37 CFR 1.704(d) “safe harbor” requires a statement that each item of information contained in the information disclosure statement: (1) was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in 37 CFR 1.56(c) more than 30 days prior to the filing of the information disclosure statement; or (2) is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in 37 CFR 1.56(c) more than 30 days prior to the filing of the information disclosure statement. 37 CFR 1.704(d)(1).

This final rule specifically revises 37 CFR 1.704(d) to include a new paragraph (d)(3) requiring applicants to submit the statement, under 37 CFR 1.704(d)(1), as required for the “safe harbor” of 37 CFR 1.704(d), on Office form PTO/SB/133 using the appropriate document code (PTA.IDS). The Office makes the patent term adjustment determination indicated in the patent with a computer program that uses the information

recorded in the Office's patent application data repository, except when an applicant requests reconsideration pursuant to 37 CFR 1.705. *See* AIPA patent term adjustment final rule, 65 FR at 56381. When an applicant uses the Office form and document code, the patent term adjustment computer program will be able to determine when the statement under 37 CFR 1.704(d)(1), as required for the "safe harbor" of 37 CFR 1.704(d), has been filed in the application.

Applicants who submit their own statement under 37 CFR 1.704(d)(1), as required for the "safe harbor" of 37 CFR 1.704(d), without using the Office form or the appropriate document code will need to request reconsideration of the patent term adjustment under 37 CFR 1.705(b) for the information disclosure statement to not be considered a failure to engage in reasonable efforts to conclude the prosecution (processing or examination) of the application. The Office conducts a manual redetermination of patent term adjustment in response to a request for reconsideration of the patent term adjustment. *See* Revisions To Implement the Patent Term Adjustment Provisions of the Leahy-Smith America Invents Act Technical Corrections Act, 79 FR 27755, 27757 (May 15, 2014). The redetermination of patent term adjustment will be based on the Office's manual review of the statement under 37 CFR 1.704(d)(1). A manual review of the statement under 37 CFR 1.704(d)(1), as required for the "safe harbor" of 37 CFR 1.704(d), is necessary when an applicant does not use Office form PTO/SB/133.

The Office has reviewed a sampling of statements under 37 CFR 1.704(d)(1) that were independently submitted without the use of Office form PTO/SB/133 and has determined that a number of those statements were deficient for failing to meet the required language of 37 CFR 1.704(d)(1). Therefore, the Office has determined that there is a need for the reconsideration procedure where the Office form PTO/SB/133 is not used.

Form PTO/SB/133 includes the patent term adjustment statement required by 37 CFR 1.704(d)(1). Specifically, the form includes the statement that “[e]ach item of information contained in the information disclosure statement was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the information disclosure statement.” The form also includes the alternative statement that “[e]ach item of information contained in the information disclosure statement is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the information disclosure statement.” Either one or both of these statements may be selected on form PTO/SB/133.

The Office has also created a particular document code (PTA.IDS) for the filing of Office form PTO/SB/133 (statement under 37 CFR 1.704(d)(1)) to facilitate the accurate electronic capture of a statement under 37 CFR 1.704(d)(1) by the Office’s patent application data repository when filed using Office form PTO/SB/133. Thus, the Office’s patent term adjustment computer program now determines when the Office form PTO/SB/133 has been filed concurrently with (i.e., on the same date as) the information disclosure statement based on the application data in the Office’s Patent Application Locating and Monitoring (PALM) system and will take the statement under 37 CFR 1.704(d)(1) into account when calculating patent term adjustment. The document code (PTA.IDS) is included on Office form PTO/SB/133. While the Office encourages the filing of correspondence via the USPTO patent electronic filing system, the inclusion of this document code (PTA.IDS) on the form PTO/SB/133 satisfies the “using the appropriate document code (PTA.IDS)” requirement of 37 CFR 1.704(d)(3) for

statements under 37 CFR 1.704(d)(1) not submitted via the USPTO patent electronic filing system.

Use of form PTO/SB/133 and its document code (PTA.IDS) aims to: (1) ensure the accurate capture by the Office's PALM system of the presence of a statement under 37 CFR 1.704(d)(1), as required for the "safe harbor" of 37 CFR 1.704(d); and (2) eliminate the need to manually review an applicant's statement under 37 CFR 1.704(d)(1) to determine whether it is proper under 37 CFR 1.704(d)(1). Furthermore, as a result of using form PTO/SB/133 and its document code (PTA.IDS), the Office's automated process for calculating patent term adjustment will be more likely to account for the statement under 37 CFR 1.704(d)(1), thereby reducing the situations in which a request for reconsideration of patent term adjustment under 37 CFR 1.705(b) is necessary. Form PTO/SB/133 is available at [www.uspto.gov/sites/default/files/documents/sb0133.pdf](http://www.uspto.gov/sites/default/files/documents/sb0133.pdf). The Office of Management and Budget (OMB) has determined that, under 5 CFR 1320.3(h), form PTO/SB/133 does not collect "information" within the meaning of the Paperwork Reduction Act of 1995.

Applicants may no longer use the document code PTA.IDS, which is specific to Office form PTO/SB/133, for filing a statement under 37 CFR 1.704(d)(1) unless they are using Office form PTO/SB/133. Applicants filing a statement under 37 CFR 1.704(d)(1) without Office form PTO/SB/133 may only use the document code PTA.IDS for the submission of an information disclosure statement. The presentation to the Office (whether by signing, filing, submitting, or later advocating) of form PTO/SB/133, whether by a practitioner or non-practitioner, is a certification under 37 CFR 11.18(b) that the existing text and any certification statements on the form have not been altered. The use of the document code PTA.IDS specifically for form PTO/SB/133 is a representation that the applicant is filing form PTO/SB/133 with no alterations to the text of the form.

Applicants who submit a statement under 37 CFR 1.704(d)(1) in any manner other than on Office form PTO/SB/133 will be treated as not having submitted the statement, under 37 CFR 1.704(d)(1), as required for the “safe harbor” of 37 CFR 1.704(d). In addition, applicants who submit a statement under 37 CFR 1.704(d)(1) on Office form PTO/SB/133 with any modification to the statement under 37 CFR 1.704(d)(1) on the form (that is, modifications to either or both of the statements indicated on the form) will be treated as not having submitted the statement, under 37 CFR 1.704(d)(1), as required for the “safe harbor” of 37 CFR 1.704(d). Under such circumstances, applicants will need to request reconsideration of the patent term adjustment, under 37 CFR 1.705(b) for the paper or request for continued examination, to be treated as having been filed concurrently with the statement, under 37 CFR 1.704(d)(1), as required for the “safe harbor” of 37 CFR 1.704(d).

The submission of a statement under 37 CFR 1.704(d)(1) does not require a fee. However, in certain cases, a fee is required for the Office to consider a statement under 37 CFR 1.704(d)(1) in a patent term adjustment determination. Specifically, the Office has provided a procedure for applicants to seek a waiver under 37 CFR 1.183 to allow for a late-filed statement under 37 CFR 1.704(d)(1). A petition under 37 CFR 1.183 provides for suspension of rules and requires the fee under 37 CFR 1.17(f). If an applicant submits an information disclosure statement within the 30-day period set forth in 37 CFR 1.704(d)(1) but does not include a statement under 37 CFR 1.704(d)(1) with the information disclosure statement, the applicant should consider filing a request for reconsideration of the patent term adjustment indicated on the patent (37 CFR 1.705(b)), along with a statement under 37 CFR 1.704(d)(1) (if not previously filed) and petition under 37 CFR 1.183 requesting that the Office consider a statement under 37 CFR 1.704(d)(1) when making the patent term adjustment determination. However, the Office will reevaluate the practice of considering such petitions under 37 CFR 1.183 now that



the patent term adjustment computer program has been updated to account for submission via Office form PTO/SB/133. The Office will provide notice prior to making any changes to this procedure.

Applicants should keep in mind that a petition under 37 CFR 1.183 may only be used to request acceptance of the late-filed statement under 37 CFR 1.704(d)(1). Under no circumstances will an information disclosure statement filed more than 30 days from the applicable communication under 37 CFR 1.704(d)(1)(i) or (ii) be treated as filed within the “safe harbor” of 37 CFR 1.704(d). In addition, the 30-day period in 37 CFR 1.704(d)(1) is not extendable (see 37 CFR 1.704(d)(2)).

#### **Discussion of Specific Rules:**

The following is a discussion of the amendment to 37 CFR part 1 in this final rule.

*Section 1.704:* Section 1.704(d) as amended in this final rule includes a new § 1.704(d)(3) requiring that the statement under § 1.704(d)(1) be submitted on a form provided by the Office (PTO/SB/133) using the appropriate document code (PTA.IDS). New § 1.704(d)(3) also provides that if the statement under § 1.704(d)(1) is not submitted on a form provided by the Office (PTO/SB/133) using the appropriate document code (PTA.IDS), the paper or request for continued examination will be treated as not accompanied by a statement under § 1.704(d)(1), unless an application for patent term adjustment in compliance with § 1.705(b) is filed, establishing that the paper or request for continued examination was accompanied by a statement in compliance with § 1.704(d)(1). New § 1.704(d)(3) provides that: (1) no changes to statements on this Office form may be made; and (2) the presentation of this form to the Office, whether by signing, filing, submitting, or later advocating, and whether by a practitioner or non-practitioner, constitutes a certification under 37 CFR 11.18(b) that the existing text and any certification statements on this form have not been altered.

### **Changes From the Proposed Rule:**

This final rule contains two changes from the proposed rule. First, the final rule replaces the proposed provision that a statement under § 1.704(d)(1) must be submitted on the Office form (PTO/SB/133) or the paper or request for continued examination will be treated as not accompanied by a statement under § 1.704(d)(1), with a new provision that a statement under § 1.704(d)(1) must be submitted on the Office form (PTO/SB/133) or the paper or request for continued examination will be treated as not accompanied by a statement under § 1.704(d)(1) unless an application for patent term adjustment (§ 1.705(b)) is filed, establishing that the paper or request for continued examination was accompanied by a statement in compliance with § 1.704(d)(1). Thus, this final rule allows applicants who provided a statement under § 1.704(d)(1) not using the Office form PTO/SB/133 with an avenue to have the statement given effect when determining the patent term adjustment. Second, this final rule clarifies that the form provided by the Office (PTO/SB/133) must be submitted using the appropriate document code (PTA.IDS).

### **Comments and Responses to Comments:**

*Comment 1:* One commenter suggested that the Office continue the current practice of permitting an applicant to make the required safe harbor statement(s) in any paper filed on the same date as the information disclosure statement, but require the applicant to request reconsideration of the patent term adjustment under § 1.705(b) to invoke the safe harbor if form PTO/SB/133 was not used. Another commenter expressed sympathy for the purpose of the rule change but opposed it because the Office has plenty of alternative methods to educate the public in reducing errors in the certificate statement.

*Response:* Section 1.704(d)(3), as adopted in this final rule, requires that the statement under § 1.704(d)(1) be submitted on a form provided by the Office (PTO/SB/133) using the appropriate document code (PTA.IDS). Section 1.704(d)(3) also

provides that if the applicant does not use the Office form and its document code (PTA.IDS), the paper or request for continued examination will be treated as not accompanied by a statement under § 1.704(d)(1) unless an application for patent term adjustment in compliance with § 1.705(b) is filed, establishing that the paper or request for continued examination was accompanied by a statement in compliance with § 1.704(d)(1). Moreover, the Office will provide additional information and educate the public by providing examples in which the Office deemed the statement not sufficient to comply with the requirements of § 1.704(d)(1).

*Comment 2:* One commenter advised the Office that the electronic form would not allow for checking both boxes, and thus they had to file two forms to address statements under each provision.

*Response:* In response to this comment, the Office form PTO/SB/133 has been revised so an applicant can make the statement under § 1.704(d)(1)(i) or (ii), or both §§ 1.704(d)(1)(i) and (ii).

*Comment 3:* Two commenters suggested that the Office consider modifying the language of the form PTO/SB/133 to address concerns about what is being asserted when both boxes on the form are checked.

*Response:* Sections 1.704(d)(i) and 1.704(d)(ii) are distinct conditions. When an applicant checks both boxes on form PTO/SB/133, the applicant is asserting that each cited reference meets the conditions of § 1.704(d)(1)(i) or 1.704(d)(1)(ii).

In 2011, the Office added § 1.704(d)(1)(ii) to extend the “safe harbor” provision of § 1.704(d) to embrace information first cited in a communication from the Office, as well as the communication. *See* Revision of Patent Term Adjustment Provisions Relating to Information Disclosure Statements, 76 FR 74700 (Dec. 1, 2011).

*Comment 4:* One commenter asked whether the rule change would be retroactively applied. The commenter further asked what an applicant should do if they had previously filed a statement under § 1.704(d).

*Response:* The changes to the rules of practice pertaining to patent term adjustment are set to go into effect on the effective date of this final rule, and are applicable to any statement under § 1.704(d) filed on or after the effective date of this final rule. The Office will apply the interim procedure for patentees to request a recalculation of their patent term adjustment determination for alleged failure to recognize that an information disclosure statement was accompanied by a safe harbor statement, by submitting a request for recalculation of patent term adjustment using Office form PTO/SB/134, for applicants who filed a statement under § 1.704(d) prior to the effective date of the change to § 1.704(d) in this final rule. *See* Interim Procedure for Requesting Recalculation of the Patent Term Adjustment With Respect to Information Disclosure Statements Accompanied by a Safe Harbor Statement, 83 FR 55102 (Nov. 2, 2018).

*Comment 5:* One commenter presented a number of scenarios and requested advice on whether an applicant could file a statement under § 1.704(d)(1) in these scenarios. The commenter also requested clarification of the definition of certain terms found in § 1.704(d)(1).

*Response:* The Office did not propose any changes to the statement required by § 1.704(d)(1) and is not adopting any changes to the statement required by § 1.704(d)(1) in this final rule. As such, this comment is outside the scope of this action. However, for information on the terms used in, and the application of, § 1.704(d)(1), the Office refers the commenter to the Office's guidance on patent term adjustment. Specifically, the statement required by § 1.704(d)(1) to take advantage of the "safe harbor" of § 1.704(d) is set forth in chapter 2700 of the Manual of Patent Examining Procedure (MPEP) (9th

ed., rev. 7.2022, February 2023), which may be viewed or downloaded free of charge from the USPTO website at <https://www.uspto.gov/MPEP> and is available to search online at <https://mpep.uspto.gov>.

### **Rulemaking Considerations**

**A. *Administrative Procedure Act*:** The changes in this rulemaking involve rules of agency practice and procedure, and/or interpretive rules. *See Perez v. Mortg. Bankers Ass’n*, 135 S. Ct. 1199, 1204 (2015) (Interpretive rules “advise the public of the agency’s construction of the statutes and rules which it administers.” (citation and internal quotation marks omitted)); *Nat’l Org. of Veterans’ Advocates v. Sec’y of Veterans Affairs*, 260 F.3d 1365, 1375 (Fed. Cir. 2001) (rule that clarifies interpretation of a statute is interpretive); *Bachow Commc’ns Inc. v. FCC*, 237 F.3d 683, 690 (D.C. Cir. 2001) (Rules governing an application process are procedural under the Administrative Procedure Act.); *Inova Alexandria Hosp. v. Shalala*, 244 F.3d 342, 350 (4th Cir. 2001) (Rules for handling appeals were procedural where they did not change the substantive standard for reviewing claims.). This final rule revises 37 CFR 1.704(d) to require that the statement under 37 CFR 1.704(d)(1) be submitted on the Office form PTO/SB/133 using the appropriate document code (PTA.IDS). This final rule also provides that, if an applicant submits their own statement under 37 CFR 1.704(d)(1), as required for the “safe harbor” of 37 CFR 1.704(d), an applicant will need to request reconsideration of the patent term adjustment under 37 CFR 1.705(b) for the Office to consider a statement under 37 CFR 1.704(d)(1) when making a determination of the patent term adjustment.

Accordingly, prior notice of and an opportunity for public comments on the changes in this rulemaking are not required pursuant to 5 U.S.C. 553(b) or (c), or any other law. *See Perez*, 135 S. Ct. at 1206 (Notice-and-comment procedures are required neither when an agency “issue[s] an initial interpretive rule” nor “when it amends or repeals that interpretive rule.”); *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336-37

(Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), do not require notice-and-comment rulemaking for “interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice” (quoting 5 U.S.C. 553(b)(A))). However, the Office chose to seek public comments before implementing the rule to benefit from the public’s input.

***B. Regulatory Flexibility Act:*** For the reasons set forth in this notice, the Senior Counsel for Regulatory and Legislative Affairs, Office of General Law, of the USPTO has certified to the Chief Counsel for Advocacy of the Small Business Administration that changes in this rule will not have a significant economic impact on a substantial number of small entities. *See* 5 U.S.C. 605(b).

This rulemaking does not impose any additional fees on applicants. This final rule revises 37 CFR 1.704(d) to require that the statement under 37 CFR 1.704(d)(1) be submitted on the Office form PTO/SB/133 using the appropriate document code (PTA.IDS), and to provide that if an applicant submits their own statement under 37 CFR 1.704(d)(1), as required for the “safe harbor” of 37 CFR 1.704(d), the applicant will need to request reconsideration of the patent term adjustment under 37 CFR 1.705(b) for the Office to consider a statement under 37 CFR 1.704(d)(1) when making a determination of the patent term adjustment. This new requirement only seeks to facilitate the current statement requirement, pursuant to 37 CFR 1.704(d)(1) and set forth in MPEP 2732, subsection IV, through the use of an existing Office form containing the required statement language.

For the foregoing reasons, the changes in this rule will not have a significant economic impact on a substantial number of small entities.

***C. Executive Order 12866 (Regulatory Planning and Review):*** This rulemaking has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993).

***D. Executive Order 13563 (Improving Regulation and Regulatory Review):*** The Office has complied with Executive Order 13563 (Jan. 18, 2011). Specifically, the Office has, to the extent feasible and applicable: (1) made a reasoned determination that the benefits justify the costs of the rule; (2) tailored the rule to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole, and provided online access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across Government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

***E. Executive Order 13132 (Federalism):*** This rulemaking does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

***F. Executive Order 13175 (Tribal Consultation):*** This rulemaking will not: (1) have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under Executive Order 13175 (Nov. 6, 2000).

***G. Executive Order 13211 (Energy Effects):*** This rulemaking is not a significant energy action under Executive Order 13211 because this rulemaking is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a

Statement of Energy Effects is not required under Executive Order 13211

(May 18, 2001).

***H. Executive Order 12988 (Civil Justice Reform):*** This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).

***I. Executive Order 13045 (Protection of Children):*** This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).

***J. Executive Order 12630 (Taking of Private Property):*** This rulemaking will not effect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

***K. Congressional Review Act:*** Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801-808), the USPTO will submit a report containing any final rule resulting from this rulemaking and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the Government Accountability Office. The changes in this rulemaking are not expected to result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this rulemaking is not a “major rule” as defined in 5 U.S.C. 804(2).

***L. Unfunded Mandates Reform Act of 1995:*** The changes set forth in this rulemaking do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of \$100 million (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of \$100 million (as adjusted) or more in any one



year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. *See* 2 U.S.C. 1501 et seq.

***M. National Environmental Policy Act of 1969:*** This rulemaking will not have any effect on the quality of the environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. *See* 42 U.S.C. 4321 et seq.

***N. National Technology Transfer and Advancement Act of 1995:*** The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are not applicable because this rulemaking does not contain provisions that involve the use of technical standards.

***O. Paperwork Reduction Act of 1995:*** The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) requires that the Office consider the impact of paperwork and other information collection burdens imposed on the public. The rules of practice pertaining to patent term adjustment and extension have been reviewed and approved by the OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) under OMB control number 0651-0020. Although this final rule requires the use of Office form PTO/SB/133 when making a statement under 37 CFR 1.704(d)(1), the OMB has determined that, under 5 CFR 1320.3(h), form PTO/SB/133 does not collect “information” within the meaning of the Paperwork Reduction Act of 1995. Because the changes in this rulemaking would not affect the information collection requirements or fees associated with the information collections approved under OMB control number 0651-0020 or any other information collection, the Office is not resubmitting an information collection package to the OMB for its review and approval.

Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of

information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

***P. E-Government Act Compliance:*** The USPTO is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes.

#### **List of Subjects in 37 CFR Part 1**

Administrative practice and procedure, Biologics, Courts, Freedom of information, Inventions and patents, Reporting and record keeping requirements, Small businesses.

For the reasons set forth in the preamble, the USPTO amends 37 CFR part 1 as follows:

#### **PART 1 - RULES OF PRACTICE IN PATENT CASES**

1. The authority citation for 37 CFR part 1 continues to read as follows:

**Authority:** 35 U.S.C. 2(b)(2), unless otherwise noted.

2. Section 1.704 is amended by adding paragraph (d)(3) to read as follows:

##### **§ 1.704 Reduction of period of adjustment of patent term.**

\* \* \* \* \*

(d) \* \* \*

(3) The statement under paragraph (d)(1) of this section must be submitted on the Office form (PTO/SB/133) provided for such a patent term adjustment statement using the appropriate document code (PTA.IDS). Otherwise, the paper or request for continued examination will be treated as not accompanied by a statement under paragraph (d)(1) of this section unless an application for patent term adjustment, in compliance with § 1.705(b), is filed, establishing that the paper or request for continued examination was accompanied by a statement in compliance with paragraph (d)(1) of this section. No

changes to statements on this Office form may be made. The presentation to the Office (whether by signing, filing, submitting, or later advocating) of this form, whether by a practitioner or non-practitioner, constitutes a certification under § 11.18(b) of this chapter that the existing text and any certification statements on this form have not been altered.

\* \* \* \* \*

**Katherine K. Vidal,**

*Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.*

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